DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 28, 2014

MEDCOMP®
Timothy Holwick
Regulatory Associate
1499 Delp Drive
Harleysville, PA 19438

Re: K130889
Trade/Device Name: Split Cath® Rg
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: March 17, 2014
Received: March 18, 2014

Dear Timothy Holwick,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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Indications for Use

510(k) Number (if known): K130889

Device Name: Split Cath® Rg

Indications for Use:

The Medcomp Split Cath® Rg is indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis in the adult patient.

It may be inserted percutaneously and is primarily placed in the internal jugular vein. Alternate insertion sites include the subclavian vein and femoral vein.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Section 5 **510(k) SUMMARY** **Traditional 510K**

Submitter Information:

Submitter: MEDCOMP®
1499 Delp Drive
Harleysville, PA 19438
(215) 256-4201 Telephone
(215) 256-9191 Fax
Contact: Timothy Holwick, Regulatory Associate
Date Prepared: March 25, 2013

Device Name: Split Cath® Rg
Common Name: Catheter, Hemodialysis, Implanted
Classification Name: Blood Access device and accessories
C.F.R. Section: 876.5540
Classification Panel: Gastroenterology and Urology
Class: III, MSD

Predicate Devices:

K121848, Split Cath® III concurrence date September 21, 2012. Class III CFR §876.5540
K022678 Split Cath IV (Split Stream), concurrence date February 24, 2003 Class III CFR §876.5540

Device Description:

The Split Cath® Rg Long Term Catheter provides two dedicated (arterial/venous) access lumens. Each lumen is connected through an extension line with female luer connectors. The transition between lumen and extension is housed within a molded hub. To prevent recirculation, the venous end of the lumen is approximately 1.0" longer than the arterial. The catheter is capable of providing consistent flows up to 400ml/min.

The catheter lumen is composed of a soft, thermo-sensitive, polyurethane material that is rigid upon insertion and once it reaches body temperature becomes soft to reduce vessel trauma.

The dialysis extensions are color coded with a white luer, red sleeve, and red clamp for the arterial lumen. The easy identification of the venous lumen, there is a white luer, blue sleeve, and blue clamp.

The proposed device is 14 French in size and comes in the following lumen lengths: 24, 28, 32, 36, and 40cm. The catheter is packaged in separate components as they are assembled during retrograde insertion. After the lumen is inserted, it is attached to the Attachable Hub and Extension Assembly using the Lumen Clamp.

Intended Used:

The Medcomp Split Cath® Rg is intended for use in attaining long term vascular access for Hemodialysis and Apheresis in the adult patient.

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Indications for Use:

The Medcomp Split Cath® Rg is indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis in the adult patient.

It may be inserted percutaneously and is primarily placed in the internal jugular vein. Alternate insertion sites include the subclavian vein and femoral vein.

Comparison to Predicate Devices:

The Split Cath® Rg is substantially equivalent to the predicate devices in terms of intended use, materials, anatomical location, basic design, performance, labeling, manufacturing process and method of sterilization.

ATTRIBUTE	Split Cath RG (Proposed Device)	Split Cath III K121848 (Predicate Device)
INDICATIONS FOR USE	The Medcomp Split Cath Rg is indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis.	The Medcomp Split Cath III is indicated for use in attaining long term vascular access for Hemodialysis and Apheresis in the adult patient.
TARGET POPULATION	Adult	Adult
INSERTION SITE	Internal jugular vein Subclavian vein	Internal jugular vein Subclavian vein Femoral vein Translumbar
WHERE USED	Hospital	Hospital
STERILIZATION METHOD	100% Ethylene Oxide	100% Ethylene Oxide
MATERIAL / ADDITIVES	Lumen - Polyurethane: ChronoFlex Cuff - Polyester Hub/Suture Wing and Luers: Isoplast Extension: Polyurethane Clamps - Acetal Extension Sleeve - Silicone Cannula and Pins - Stainless Steel	Lumen - Polyurethane: ChronoFlex Cuff - Polyester Hub and Suture Wing - Polyurethane Extension – Polyurethane Clamps - Acetal Luers - Isoplast Extension Sleeve - Silicone
DESIGN SPECIFICATION	**LUMEN:** 14F **LUMEN LENGTHS:** 24, 28, 32, 36, and 40cm	**LUMEN:** 14F **LUMEN LENGTHS:** 20, 22, 24, 28, 32, 36, 40, and 55cm

Performance Standards:

Performance standards have not been established by the FDA under section 514 of the Federal Food, Drug and Cosmetic Act.

Biocompatibility:

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Results for all biocompatibility testing demonstrate the materials used meet the requirements of ISO 10993.

Nonclinical Testing:

Performance Bench Testing:

- Air Leakage
- Liquid Leakage
- Force at Break
- Recirculation
- Flow vs. Pressure
- Priming Volume

In addition to the above testing, mechanical hemolysis testing was performed on the proposed device due to the change in blood flow path when compared to the predicate device. Furthermore, the proposed device was evaluated for MRI safety due to the presence of the stainless steel cannula.

Technological Characteristics:

The proposed device is intended for retrograde insertion whereas the predicate device is intended for antegrade insertion. To facilitate this retrograde insertion, the proposed device is packaged in a disassembled form to allow for insertion personnel to assemble the hub assembly once the lumen has been inserted and tunneled back to the insertion site.

In order to facilitate proper connection between the lumen and hub assembly, the hub assembly is outfitted with a stainless steel cannula that is not present in the predicate device. The sure fit of this cannula to lumen, followed by application of the compression ring and hub clamps, is essential to device integrity following the insertion and assembly procedure.

Once inserted and assembled, the principles of operation with regard to hemodialysis are the same as the predicate devices. There are no new questions raised regarding the safety or effectiveness of the device.

Summary of Substantial Equivalence:

In this submission, testing is provided to address the difference in technological characteristics between the proposed and predicate devices. Nonclinical testing and discussion of previously submitted information on the predicate devices establish that there are no new issues of safety or effectiveness for the proposed device.

The proposed device meets the performance criteria of design verification as specified by ISO standards, guidance documents and test protocols. The proposed device has the same intended use, operation and function as the predicates. There are no differences that raise new issues of safety and effectiveness. The proposed device is substantially equivalent to the legally marketed predicate devices.